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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,630	04/07/2005	Leanne Gail Robinson	Leanne	7027

7590 12/08/2008

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EXAMINER	
SAUCIER, SANDRA E	
ART UNIT	PAPER NUMBER
1651	
MAIL DATE	DELIVERY MODE
12/08/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,630	ROBINSON ET AL.	
	Examiner	Art Unit	
	Sandra Saucier	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *10-18,20 and 21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,19 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/7/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-22 are pending. Claims 1-9, 19, 22 are considered on the merits. Claims 10-18, 20, 21are withdrawn from consideration as being drawn to a non-elected invention.

Election/Restriction

Claims 10-18, 20, 21 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention. Election was made without traverse in Paper No. 10/14/08.

Information Disclosure Statement

The listing of the references on PTO 1449 is incomplete. 37 CFR 1.98(b) requires that each reference be completely identified.

For internet citations see MPEP 707.05(e) where multiple examples are given.

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¶

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Applicant's election with traverse of x in the reply filed on x is acknowledged. The traversal is on the ground(s) that x. This is not found persuasive because x.¶
¶
The requirement is still deemed proper and is therefore made FINAL.¶
¶
Specification¶
The disclosure is objected to because of the following informalities: ¶
¶
Appropriate correction is required.¶

>IV. < ELECTRONIC DOCUMENTS

An electronic document is one that can be retrieved from an online source (e.g., the Internet, online database, etc.) or sources found on electronic storage media (e.g., CD-ROM, magnetic disk or tape, etc.). Many references in paper format may also be retrieved as electronic documents. Other references are retrievable only from electronic sources.

The U.S. Patent and Trademark Office follows the format recommended by World Intellectual Property Organization (WIPO) Standard ST.14, "Recommendation for the Inclusion of References Cited in Patent Documents." The format for the citation of an electronic document is as similar as possible to the format used for paper documents of the same type, but with the addition of the following information in the locations indicated, where appropriate:

(A) the type of electronic medium provided in square brackets [ ] after the title of the publication or the designation of the host document, e.g., [online], [CD-ROM], [disk], [magnetic tape];

(B) the date when the document was retrieved from the electronic media in square brackets following after the date of publication, e.g., [retrieved on March 4, 1998], [retrieved on 1998-03-04]. The four-digit year must always be given.

(C) identification of the source of the document using the words "Retrieved from" and its address where applicable. This item will precede the citation of the relevant passages.

(D) specific passages of the text could be indicated if the format of the document includes pagination or an equivalent internal referencing system, or by the first and last words of the passage cited.

Office copies of an electronic document must be retained if the same document may not be available for retrieval in the future. This is especially important for sources such as the Internet and online databases.

If an electronic document is also available in paper form it does not need to be identified as an electronic document, unless it is considered desirable or useful to do so.

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Claim Objections

Claims 1, 3, 6, 9, 19 are objected to because of the following informalities: *Lactobacillus* in claims 1, 19 should be capitalized and in italics as it is a genus name. Also, in claims 3, 6, 9 the species name should not be

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capitalized, i.e. *Lactobacillus acidophilus* for example. Appropriate correction is required.

Claim Rejections – 35 USC § 112

INDEFINITE

Claims 1-9, 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "at least about", which is indefinite. The value is either at least 1 or about 1. Use of the two modifiers together defies logic as the value may be less than 1, but must be at least 1. Thus, the metes and bounds of the claim cannot be determined, see ***Amgen, Inc. v Chugai Pharmaceutical Co.***, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991) and MPEP 2173.05(b) A.

Claim 2 fails to further limit claim 1.

Claim 6 has no antecedent basis for the recitation "protein byproducts".

In claims 5 and 22, the step of replacing the by-pass or by-product protein is indefinite since the feed in the preamble of the claim is not required to have by-product protein in it to be replaced, that is, removed. Thus, this step is simply considered to be a step of adding the additive to a feed which does not contain by-pass (by product) protein, which may be considered to be an animal derived product.

WRITTEN DESCRIPTION

Claims 1-9, 19, 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

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Claim rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. ¶
¶
Insertion of the limitation x has no support in the as-filed specification. The insertion of this limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genus which would show possession of the concept of the use of x. There is only one exemplified x. This is not sufficient support for the new genus x. This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate the possession of a concept after the fact. Thus, the insertion of x is considered to be the insertion of new matter for the above re... [1]

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Claims 1-9, 19, 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention is directed to a method of feeding cattle comprising adding at least about 1unit fibrolytic enzymes to 1 X 10^5 CFU of *Lactobacillus* to the feed without ensilage, feeding the cattle. Dependent claims are further directed to types of fibrolytic enzymes and species of *Lactobacillus*.

The guidance in the specification appears to be directed solely to commercially available "fibrolytic" enzyme and microbial preparations. Yet the claims broadly claim the use of fibrolytic enzymes and *Lactobacillus*. There are many problems with this broad claiming.

The first is that the enzyme preparations vary over time and there is no complete disclosure in the specification as to what the exact contents of any of the commercial preparation are. Exact contents means identity and quantity both. The commercial products have great variability in the relative proportions of the enzymes in them and may include many enzymes besides cellulase, hemi-cellulase, xylanase such as amylases, proteases, pectinases. See Beauchemin *et al.* [U] for a discussion of the variability of the commercial products with respect to the types of enzyme content (page E38) which varies with the fungus strain employed, culture conditions and growth substrate. Thus, not all commercial products are the same and they do not all have the same mixture of "fibrolytic" enzymes.

Another is that the conditions for the measurement of units of activity are not given, that is, the temperature, time, substrate, pH etc. are not given. Any determination of enzyme activity requires these parameters. The measurement of enzyme activity is a variable and depends on the manufacturer's method of

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Written description?¶
¶
¶
¶
SCOPE¶
Claim rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for , does not reasonably provide enablement for . The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to the invention commensurate in scope with these claims. ¶
nature of the invention¶
¶

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breadth of the claims¶
¶
The claims encompass feeding all "fibrolytic enzymes" and ... [2]

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expressing the activity and the conditions of the assays used (Beauchemin *et al.* [U], page E39).

Another is that the components of the ruminant enzyme products change over time according to the desire of the manufacturer (Beauchemin *et al.* [U], page E39).

Yet another is that the effects of enzyme addition are influenced by factors such as type of diets fed to the cattle enzyme application methods (Beauchemin *et al.* [U], page E42).

Thus, the invention is incompletely described because of the use of commercial products which may be trade secrets and/or incompletely described for the reasons above.

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Thus, the specification fails to completely describe how to make and use the composition for at least the reasons above, and the specification fails to reasonably convey that the inventor had possession of the claimed invention.

Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd., 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir.1991) ("it is well established in our law that conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials, and to describe how to obtain it").

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The Federal Circuit has explained that a specification cannot always support expansive claim language and satisfy the requirements of 35 U.S.C. 112 "merely by clearly describing one embodiment of the thing claimed." *LizardTech v. Earth Resource Mapping, Inc.*, 424 F.3d 1336, 1346, 76 USPQ2d 1731, 1733 (Fed. Cir. 2005).

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NEW MATTER

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Claim 22 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Claim 22 fails to include *Lactobacillus* in the additive composition. The original claims, abstract and specification all require both fibrolytic enzymes and *Lactobacillus* in the additive.

Claim Rejections – 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action: A person shall be entitled to a patent unless (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent, (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, 19, 22 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 96/17525 [N].

The claims are directed to a method of feeding cattle comprising adding fibrolytic enzyme and *Lactobacillus* to feed without ensilage and feeding the cattle.

The reference is relied upon as explained below.

WO 96/17525 disclose treating livestock to maintain or increase weight or milk production comprising administering two or more of a) an obligate anaerobe, b) a facultative anaerobe such as lactic acid bacteria and c) one or more enzymes capable of degrading starch or fiber, see claims 1, 3 and 28. The enzymes are added to the feed without ensilage at between 60-600 units and the *Lactobacillus acidophilus* is at between $1X10^3$ and $1X10^{11}$ (page 10) and Examples 3-5. None of the feed mentioned in the publication contains animal protein.

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¶
Undue experimentation would be required to practice the invention as claimed due to the amount of experimentation necessary because of the limited amount of guidance and limited number of working examples in the specification, the nature of the invention, the state of the prior art, breadth of the claims and the unpredictability of the art.¶
¶
As set forth in In re Fisher, 427 F2.d 833, 839, 166 USPQ 18, 24 (CCPA) 1970: [Section 112] requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.¶
¶
In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of the enablement varies inversely with the degree of unpredictability of the factors involved. Ex parte Humphreys, 24 USPQ2d, 1260.¶
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Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action: (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9, 19, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 96/17525 [N].

The claims have been discussed above and are further directed to the origin of the enzymes such as being obtained from *Trichoderma viride*, *Aspergillus oryzae*, *Aspergillus niger* and *Bacillus subtilis*.

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The reference has been discussed above.

As long as the enzymes have the same enzymatic activity, i.e., xylanase and cellulase activity, the specific origin of the fibrolytic enzymes is considered to be an element of experimental design, in the absence of evidence of criticality of the origin.

With regard to the functional language used to describe the dosages given to the cattle which merely describes a desired result, in the absence of evidence to the contrary, the ranges of the dosages taught in WO 96/17525 are considered to be at least overlapping.

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With regard to the differences in concentrations between the instant claims and the disclosure of the prior art, see MPEP 2144.05 I. and II.

In the case where the claimed ranges overlap or lie inside ranges disclosed by the prior art, a *prima facie* case of obviousness exists.

Generally differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

One of ordinary skill in the art would have been motivated at the time of invention to make this substitution or enzyme origins in order to obtain the resulting composition as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

REQUIREMENT UNDER 37 CFR 1.105

Applicant and the assignee of this application are required under 37 CFR 1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application.

An issue of public use or on sale activity has been raised in this application. In order for the examiner to properly consider patentability of the claimed invention under 35 U.S.C. 102(b), additional information regarding this issue is required as follows:

On page 7 of the specification it states "The present inventors market a product containing lactobacillus and an enzyme system. The composition was a trade secret. The ratio of....

The questions to be answered are 1) what date did the product go on sale, 2) where was it on sale, 3) what information about the product was used in

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¶
Claim rejected under 35 U.S.C. 103(a) as being unpatentable over as applied to claim above, and further in view of .¶
¶
The claims are further directed to¶

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marketing, such as the labeling of the product or the insert with instruction on how to use associated with the product, 4) what exactly were the components and concentration of the components of the product on sale. A copy of all text associated with the commercial product is required.

Applicant is reminded that failure to fully reply to this requirement for information will result in a holding of abandonment.

See MPEP 704.10 and 704.11 for guidelines concerning a requirement for information which is made by the examiner.

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Conclusion

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Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). It is applicants' burden to indicate how amendments are supported by the ORIGINAL disclosure. Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending applications that set forth similar subject matter to the present claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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/Sandra Saucier/
Primary Examiner
Art Unit 1651